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A New Approach to Orthopaedic Implant Design

K. Hollerbach, S. Perfect, H. Martz, E. Ashby

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A New Approach to Orthopaedic Implant Design

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LDRD Investigators:
Karin Hollerbach, Institute for Scientific Computing Research
(now in Computer Systems Research Group, EETD)
Scott Perfect, New Technologies Engineering Division
Harry Martz, Manufacturing & Materials Engineering Division
Elaine Ashby, Mechanical Engineering

Abstract

This report describes the accomplishments of a three year LDRD project, aimed at developing computational models and methodologies for improving prosthetic joint design. The investigators developed human models as well as prosthetic joint models. Input data came both from high resolution scans performed at Lawrence Livermore National Laboratory (LLNL) and from data provided by collaborators. Results of our approach, in addition to being presented at scientific meetings, are being used to obtain U.S. Food and Drug Administration (FDA) approval in the process of putting new implant designs on the market.

Introduction

Total joint replacement has become a major industry and will expand dramatically as our population ages and our life expectancy increases. However, the present joint replacement market is served by an inadequate product. As a group, US implant recipients can anticipate needing multiple revision surgeries. The failure of most implants to reproduce normal joint kinematics results from a lack of understanding of specific joint kinematics and a lack of means to quantitatively assess the effects of implant geometry modification on the kinematics of the implanted joint. Material failure is common at the articular surfaces. The most commonly used material for the articular surfaces is ultra-high molecular weight polyethylene (UHMWPE). Factors cited in determining the survivability of polyethylene components include manufacturing processes, component thickness, and articulating surface geometry. Positive correlations have been found between the degree of wear and nonconformity of the prosthesis, high contact pressure, and thin polyethylene tibial components. Bone-implant interface failure can lead to bone fracture and implant loosening. There is a clear need for an improved approach to implant design, to minimize the number of costly and risky revision surgeries that implant patients are likely to face.

The approach of this LDRD project has been to develop methodologies that allow prosthetic designers to predict the behavior of implant designs under conditions as they would appear in the body. This has been accomplished using finite element modeling, which offers an opportunity to evaluate designs before they are manufactured or surgically implanted. This approach has been applied as an alternative to current methods that use only expensive, time-consuming experimental testing for design evaluation, where retrieved implants serve as a post-failure demonstration of poor design strategies. Results of our approach, in addition to being presented at scientific meetings, are being used to obtain FDA approval in the process of putting new implant designs on the market.

The prosthetic modeling work has involved several outside collaborators, including Dr. A. Hollister, an orthopaedic surgeon at the Louisiana State University Medical Center; ArthroMotion, ExacTech Corp., and Wright Medical, Inc. (orthopaedic companies); the University of California at Berkeley and San Francisco; and the Massachusetts General Hospital.

Accomplishments

Development of data acquisition capabilities, modeling tools, and integration of modeling process.

1) Human data acquisition

The on-site facilities and expertise of the Non-Destructive Evaluation section (NDE) in Mechanical Engineering were used to obtain computed tomography (CT) data, which were then used to determine bone and, to some degree, tendon geometry. Typically, scanners used in the medical field have a spatial resolution of up to 1 mm, which is inadequate for a precise definition of articular surfaces, as required in this application. A higher resolution can be achieved at LLNL. We have scanned multiple hands and knees, using industrial scanners that were designed and constructed at NDE, achieving spacial resolutions of up to 150 - 190 μm in all three dimensions. The LCAT scanner was used for most of our scans. It can be reconfigured to handle objects of various sizes and attenuations. LCAT makes it possible to acquire high-spatial resolution isotropic volume elements (voxels). The reconstruction step is the most computationally-intensive and was performed using a parallelized Convolution Back-Projection (CBP) algorithm. Several experiments were performed in order to assess the effects of data preprocessing and volume reconstruction. Removing bad pixels that appear when a photon hits the CCD directly made the segmentation significantly easier. The correction for beam-hardening also proved extremely useful from the segmentation point of view. Several experiments were performed in order to choose the "best" cut-off frequency for this kind of bio-tissue application, thereby extending the evaluation capabilities of NDE.

High resolution MRI data sets were also obtained from clinical collaborators at the University of California at San Francisco's Medical School (UCSF) and at the Massachusetts General Hospital (MGH). Collaborators at MGH have provided several MRI data sets of patient knees; collaborators at UCSF have provided data sets for some of the same cadaver hands used on-site for CT data acquisition. These MRI data were used in conjunction with the high resolution CT scans to help define the geometry and attachment sites for soft tissues.

2) Three-dimensional surface extraction from human data

To extract 3-D surfaces from the CT volume images, segmentation and surface reconstruction tools were developed, implemented and applied to the data. The tools have been integrated into an interactive software environment (VISU) to facilitate use by others at LLNL. Segmentation is made difficult by the inhomogeneous trabecular structure of the bones. Choosing a threshold in a robust way is almost impossible, since the initial histogram is unimodal. Similarly, edge detection methods produce a large number of spurious edges. Our approach relies on a simple model of the bone attenuation profiles. A 3-D gray-scale morphological reconstruction removes the texture and fills in the bones. This coarse segmentation is improved by computing the watershed lines, which are by construction located on gradient peaks and hence on sharp boundaries. Our attenuation model and morphological approach were satisfactory in most cases. However, human interaction will always be needed to correct the coarse segmentation or the end-result. This kind of interaction requires computational tools that allow the user to visualize large data sets, manipulate the color map to display false colors, perform interactive thresholding, overlay the segmentation mask, and save the corrected results. Polygonal surfaces were extracting using both a contour based approach and a 3-D approach, which performed well in our application, even in the case of branching or merging structures, while requiring no interaction or choice of parameters. However, the number of vertices required to represent a complex geometry is on the order of several millions. A decimation of the polygonal surface using the Decimate package helped remove approximately 70% of the vertices, by replacing small triangles in flat regions by larger ones.

3) Prosthetic joint data acquisition

Prosthetic joint data acquired from industry collaborators were provided as 3-D surface descriptions in the form of IGES (Initial Graphics Exchange Specification) files. No separate surface extraction techniques had to be applied to these data sets, although some effort at data format conversion was required in each case.

4) Material models and boundary conditions.

The experimental and modeling literature that describes the material behavior of UHMWPE was reviewed and, based on currently available data, an appropriate set of material parameters was incorporated into a NIKE material model.

Boundary conditions were taken from the literature and from experimental results provided by outside collaborators. The loading conditions and initial ligament tensions were determined from experiments performed in collaboration with our research partners at Louisiana State University Medical Center (LSUMC) and from a biomechanics model developed in collaboration with the G.W.L. Hansen's Disease Center.

<u>Finite element model development of human joints and prosthetic joint implants.</u>

A complete finite element model was developed for all hand bones, with soft tissue models developed for the thumb and index finger. In order to streamline the efficiency of finite element model development, a semi-automated approach was developed in the development of the hand model: A template based approach to hexahedral, volumetric mesh generation was developed and applied to the bones. Due to normal and sometimes pathological variations in anatomy, each person's finger bones are of a slightly different shape and size. However, since similarities usually outweigh differences, the problem of generating a mesh for each bone in all fingers of different people is greatly diminished by the development of one or more templates, each of which can be used to mesh more than one bone. In the method used to automate mesh generation, one template is chosen out of a library of templates, based on the geometry of the surface to be gridded, and then deformed to fit that geometry. A particular pre-defined (for the chosen template) sequence of steps to compute the volumetric grid is then performed.

A nonlinear, 3-D model of the index finger was developed. The model simulates index finger flexion, actuated by the displacement of the two flexor tendons, flexor digitorum profundus and flexor digitorum superficialis. The index finger model includes the bones, tendons, annular pulleys, and collateral ligaments for each of the joints, as well as the volar plate for the metacarpophalangeal joint. This is the first demonstration of a 3-D model of the full flexion of the index finger. It is based on physiologically relevant data and correlates with published data. The model's simulated motion is driven by the joint articular surfaces, not by a pre-determined kinematic model imposed on the analysis. Accurate kinematics reflect an accuracy of the model geometry and of the model's ability to simulate realistic motion. A similar, physiologically valid thumb model was created, and the effects on joint reaction forces in the thumb's carpo-metacarpal joint were shown.

The models of the hand have been presented at peer-reviewed international meetings and are now being prepared for journal publication.

The original 'high-fidelity knee model' was extended, and a new, partial knee model based on MRI data from MGH was also developed, primarily for use in a collaborative project with Lasers at LLNL, the University of California at Davis, and MGH.

<u>Industry collaborations: Analyses of prosthetic implants.</u>

Four implant designs, chosen to represent current market products and new products under development, were modeled and their behavior under physiological loading simulated. The designs were evaluated by examining the interface contact stresses and material deformation, following loading representing in vivo conditions. The designs modeled include two knee joints (ExacTech, Inc. and the Biomedical Research Foundation), a thumb carpo-metacarpal joint (Avanta Orthopaedics, Inc.), and a generic ball socket design that has been used for the thumb carpo-metacarpal joint replacement in the past and is currently being used extensively in the hip joint.

Results of these simulations were presented at national and international engineering computational, and medical meetings.

1) ExacTech, Inc.

Finite element analyses were carried out on the ExacTech Optetrak cemented total knee prosthesis, with an all-UHMWPE tibial component. The study analyzed stresses in the tibial component. Results indicated that interface stresses increased with varus rotation and knee flexion angle. There was good agreement between computational analysis results and experimental results, providing a validation of the modeling techniques.

2) Biomedical Research Foundation (BRF)

The BRF has sponsored a new knee design, to be submitted to the FDA for approval. After our computational analysis of an early design iteration indicated regions of high stress concentrations, the knee implant design was changed. Our analysis of the second design iteration, indicating some reduction in stress, was recently submitted to the BRF, which will be using the results in its submission to the FDA.

3) Avanta Orthopaedics, Inc. & generic ball and socket model

Simulation results for the thumb carpo-metacarpal joint implant correlated with clinical findings. This implant has already been on the market. Consequently our research results were not used in FDA submissions. However, this analysis helped to validate the modeling approach. The Avanta design shows greater promise than do the ball and socket and some other designs. As a result of its high failure rate, the ball and socket implant is now used less frequently in the thumb. However, a geometrically similar design is commonly used in the hip, which represents one of the largest joint replacement markets.

4) Wright Medical

A spinal fixation device design was modeled and its behavior under physiological loading simulated. Results were reported back to Wright Medical.

5) Additional industry collaborations

Additional contracts have been pursued (e.g., Ascension Orthopedics, Inc.). Together with Ascension, we have submitted a Small Business Technology Transfer proposal to the National Institutes of Health, to assist Ascension in the development of a new implant for the finger joints. We are currently awaiting the outcome of this proposal submission.

Benefits to LLNL

The work performed in this project has resulted in an extension of LLNL core competencies in non-destructive evaluation techniques, in finite element modeling techniques (using the NIKE3D code), and in computational model development techniques; furthermore, it has directly resulted several spin-off projects in the orthopedic industry (e.g., ExacTech, Wright Medical, BRF, Ascension) and in other industries (Knolls Atomic Power Laboratory). Publications and presentations have received commendation at the international level and have appeared in the engineering, computational, and medical literature.

Selected Publicationss

1998 UCRL-JC-128400 Rev. 1, The role of nondestructive evaluation in life cycle management, 3rd Annual Symposium on Frontiers in Engineering, Martz, H. E. (Invited meeting abstract)

1997 UCRL ------ Hollerbach, K. and Hollister, A., Prosthetic knee design by simulation, Biomechanics Desk Reference (Biomechanics) (Refereed journal).

1997 UCRL-JC-126796, 3-D finite element model development for joint biomechanics, VIth Intl Sym on Comp Simulation in Biomech, Hollerbach, K et al. (Meeting abstract).

1997 UCRL-JC- 126797 A computational tool for comparison of kinematic mechanisms and commonly used kinematic models", VIth Intl Sym on Comp Simulation in Biomech, Hollerbach, K et al. (Meeting abstract).

1997 UCRL-JC-127346, 3-D, nonlinear finite element analysis of prosthetic joint implants for the thumb carpornetacarpal joint, XVIth Congr of the Intl Soc of Biomech, Hollerbach, K et al. (Meeting abstract).

1997 UCRL-JC-127344, A general multi-link kinematic representation for human limbs, XVIth Congr of the Intl Soc of Biomech, Hollerbach, K et al. (Meeting abstract).

1997 UCRL-JC- 127342, A 3-D finite element model of the human index finger, XVIth Congr of the Intl Soc of Biomech, Hollerbach, K et al. (Meeting abstract).

1997 UCRL-JC- 127343, Joint coordinate system (JCS) application for different joint mechanisms: comparison of actual and JCS axes' rotations and translations, XVIth Congr of the Intl Soc of Biomech, Van Vorhis, RL et al. (Meeting abstract).

1997 UCRL-JC-127341, Errors in applying the screw deviation method to calculate motion produced by single degree of freedom mechanisms, XVIth Congr of the Intl Soc of Biomech, Hollerbach, K et al. (Meeting abstract).

1997 UCRL-JC-127345, Measurement of human wrist functional axes motions: preliminary validation of method, XVIth Congr of the Intl Soc of Biomech, Van Vorhis, RL et al. (Meeting abstract).

1997 UCRL-MI126408-(Rev. 1), Computational Biomechanics: Finite element analyses of human and prosthetic joints, Videotape, Hollerbach, K et al. (Non-refereed report).

1997 UCRL-CR- 126386, Parallel and Distributed Volume Visualization S PIE Electronic Imaging, Wittenbrink, C et al. (Meeting abstract).

1996 UCRL-JC-125155, 0 & P Computerized Prosthetic Modeling, Biomechanics, Hollerbach, K and Hollister, A. (Refereed journal).

1996 UCRL-CR- 126386, "Parallel and Distributed Volume Visualization," SPIE *Electronic Imaging,* Wittenbrink, C., et al. (Refereed meeting abstract).

1996 UCRL-JC- 124362, "Hypertools in image and volume visualization", 4th Annual Tcl/Tk Workshop, Bossart, P-L (Meeting abstract).

<u>Articles in preparation for publication in 1999.</u>

Computed tomography of human joints and radioactive waste drums, Martz, H. E., et al. (Invited paper)

A finite element study of the response to loading of a carpometacarpal joint replacement, Hollerbach, K, et al. (Refereed journal).

A 3-D finite element model of index finger flexion, Hollerbach, K, et al. (Refereed journal).

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